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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,093	06/25/2001	Sidney Pestka	PBLI-P08-005	9195

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EXAMINER

MERTZ, PREMA MARIA

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 09/891,093	Applicant(s) Sidney Pestka
Examiner Prema Mertz	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM

THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Jan 30, 2003

2b)  This action is non-final.

2a)  This action is FINAL.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 18-20, 37, and 38 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 18-20, 37, and 38 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 9

6)  Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. Amended claims 18-20, 37-38 (Paper No. 11, 1/30/03) are under consideration.
2. Receipt of applicant's arguments and amendments filed in (Paper No. 11, 1/30/03) is acknowledged.
3. The following previous rejections and objections are withdrawn in light of applicants amendments filed in (Paper No. 11, 1/30/03):
  - (i) the objection to the title of the invention;
  - (ii) the objection to the specification for reciting the old ATCC address;
  - (iii) the objection to claim 38.
4. Applicant's arguments filed in Paper No. 11, 1/30/03, have been fully considered and were persuasive in part. The issues remaining as well as new issues are stated below.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112, first paragraph***

6. Claims 18-20, 37-38 are rejected under 35 U.S.C. 112, first paragraph.  
This rejection is maintained for reasons of record set forth at pages 2-5 of the previous Office action (Paper No. 8, 9/30/02).

Applicants argue that claim 18 has been amended to recite "the interleukin-2 gene from the diseased cell hybridizes under stringent wash conditions to a normal human interleukin-2 gene" and that claim 18 now provides a further structural feature that could distinguish

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compounds in the genus from others. However, contrary to Applicants arguments, the issue here is that Applicants are not in possession of the invention as claimed. Applicants appear to have misconstrued the Examiner's rejection. The issue here is that Applicants are claiming a polypeptide which is not described in the specification. Recitation of the additional "hybridizing" language in the claims is irrelevant because the specification does not disclose or teach the modified IL-2 being claimed. The specification does not disclose a modified IL-2 polypeptide with respect to the disclosure of relevant identifying characteristics i.e. structure, other physical and/or chemical characteristics or combination of such characteristics. The description for the claimed polypeptide is limited to its function. A sequence described only by a purely functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed species. In this case, in the instant specification, Applicants have failed to describe the modified IL-2 polypeptide or the gene encoding the modified IL-2, in the absence of which one of skill in the art would not be able to make the modified IL-2 polypeptide. Thus, at the time the application was filed, the modified IL-2 polypeptide being claimed was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention.

Furthermore, with respect to the 35 U.S.C. 112, first paragraph enablement rejection, Applicants appear to have misconstrued this rejection too. Applicants argue that claim 18 has been amended to recite "the interleukin-2 gene from the diseased cell hybridizes under stringent

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wash conditions to a normal human interleukin-2 gene" and that one skilled in the art would be able to distinguish the claimed polypeptides from others. However, contrary to Applicants arguments, the issue here is that claims 18-20, 37-38, broadly encompass all IL-2 proteins comprising a modification of natural IL-2, said modified IL-2 encoded by a gene from a diseased cell. However, the specification is not enabled for a single IL-2 polypeptide having an amino acid sequence anything less than the natural IL-2. These properties of the modified IL-2 may differ structurally, chemically and physically from other known proteins.

The claimed invention encompasses modified IL-2 protein molecules not envisioned or described in the specification, and neither does the specification disclose how the recombinantly produced polypeptides can be distinguished from each other. There is not a single mutein IL-2 disclosed in the specification, which has specific properties which differ structurally, chemically and physically from other known IL-2 polypeptides. Applicants have failed to disclose which disease cells have the gene for the modified IL-2. Since Applicant has failed to disclose such, it would entail undue experimentation to screen every possible type of diseased cell known to man to determine which diseased cell contains the gene for the modified IL-2. The specification does not provide the necessary information nor the guidance to enable a skilled artisan to make all the embodiments which would be encompassed by the scope of the claims since the claims do not recite the specific properties characteristic for the claimed polypeptide. The instant disclosure is clearly insufficient support under the first paragraph of 35 U.S.C. § 112 for claims which

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encompass every and all recombinant polypeptides having the activity described in claim 37 and being derived from diseased cells.

***Claim Rejections - 35 USC § 112, second paragraph***

7. Claims 18-20, 37-38 are rejected under 35 U.S.C. 112, second paragraph.

This rejection is maintained for reasons of record set forth at pages 5-6 of the previous Office action (Paper No. 8, 9/30/02).

With respect to the limitation "is a modification of an amino acid sequence of a normal human interleukin-2", Applicants argue that claim 18 has been amended to recite "the interleukin-2 gene from the diseased cell hybridizes under stringent wash conditions to a normal human interleukin-2 gene" and that the metes and bounds of the claim are now clear. However, contrary to Applicants arguments, inspite of the amendment to claim 18, the issue here is that the claim is still unclear because the metes and bounds of the term "modification" are unclear with respect to which substitutions, deletions, additions and combinations thereof are encompassed by the claim.

Furthermore, the new limitation in claim 18 recites "hybridizes under stringent wash conditions", which term is a relative and conditional term and renders the claim indefinite. Furthermore, some nucleic acids which might remain hybridized under wash conditions of moderate stringency, for example, would fail to remain hybridized at all under conditions of high stringency. The metes and bounds of the claim thus cannot be ascertained.

With respect to the recitation of "normal human interleukin-2" in claim 18, the recitation of this term is vague and indefinite because it is unclear which IL-2 is considered "normal".

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Claims 19-20 are vague and indefinite because they recite "obtainable from leukemic leukocytes" and "obtainable from human malignancies", respectively, but the metes and bounds of "obtainable" has not been provided in the specification. It is unclear what the term means and what protein is considered "obtainable" or how the protein is "obtainable". Furthermore, the term "obtainable" renders the claims indefinite because it is unclear whether the limitations following the term are part of the claimed invention. See MPEP. § 2173.05(d).

Claims 37-38 are rejected as vague and indefinite insofar as they depend on claim 18 for its limitations.

***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 305-3014 or (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Prema Mertz*  
Prema Mertz Ph.D.  
Primary Examiner  
Art Unit 1646  
February 10, 2003